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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,397	03/25/2004	Howard R. Levin	JHN-4343-3	5537

23117 7590 09/11/2008  
NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER
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DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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09/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 4, 10-11, 15-18, 20, 23 – 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (US 4,991,578 A).

3. Cohen discloses a method of infusing fluid into the pericardial sac in order to cause pericardial effusion (Column 3, lines 20-28), which inherently constricts the heart because a hydraulic shell is formed around the heart due to the fluid being infused into the pericardial sac (and entire reference).

4. Column 10, line 60 - Column 11, line 25 deals with the catheter having a balloon at the distal end as well as disclosing the catheter with anchoring means (Column 5, lines 15-21).

5. Claims 1-4, 8-11, 13, 15-28, 36-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Snyders (US 6,095,968 A).

6. Snyders discloses a method of infusing fluid into the pericardial sac in order to cause pericardial effusion (Column 1, lines 35-51), wherein the jacket is being

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interpreted as the catheter, since it is tube like structure with a lumen. The jacket also forms a hydraulic shell surrounding the heart in the pericardial sac to reduce dilation of the heart (and entire reference).

7. Column 4, lines 6-30 deals with the pressure transducer and the pressure the jacket is suppose to be maintained between 2-10 mmHg.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5-9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen.

10. Cohen discloses the claimed invention except for the duration of the procedure as well as when to perform the procedure.

11. Therefore at the time of the invention it would have been obvious for one of ordinary skill in the art to modify the teachings of Cohen to include the specific details of the time and length of the procedure. Cohen discloses a method of implanting a defibrillation electrode into the heart with the specific procedure of infusing fluid into the pericardial sac but fails to recite the period of time as well as when to perform the procedure. Since Cohen discloses implanting a defibrillation electrode, this is usually done after a person has heart troubles and thus it would be obvious to perform this

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procedure after a person has a heart attack. Cohen also discloses a short term procedure thus it would have been obvious to infuse the fluid no greater than a day or two since the method of implanting the electrode would be performed quickly and not like the long term procedure as taught by Snyders (the other prior art reference cited in this office action) .

12. Claim 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders.

13. Snyders discloses a gravity fill pump (claim 5), but never recited the height in which the "pump" will be held.

14. At the time of the invention it would have been obvious for one of ordinary skill in the art to modify Snyders because adjusting the height of a gravity pump or hanging reservoir is routinely performed in the medical art and is determined by the medical professional performing the procedure, thus making the modification well known and routine.

### ***Response to Arguments***

15. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto

/Matthew F DeSanto/  
Primary Examiner, Art Unit 3763